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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	E	ATTORNEY DOCKET NO.
09/092,297	06/05/98	BILLING NEEDLE		ATT/15

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EXAMINER

TURNER, S

1544

PAPER NUMBER

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02/15/00

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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No. 09/092,297	Applicant Sharon L. Turner, Ph.D.	Billing-Medel Group Art Unit 1644	
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Responsive to communication(s) filed on 11-30-99

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

- Claim(s) 1-55 is/are pending in the application.  
Of the above, claim(s) 1-9, 17-24, 26-29, 31, 32, 34, 36, 37, and 40-44 is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 10-16, 25, 30, 33, 35, 38, 39, and 45-55 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims 1-55 are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit:

**Response to Amendment**

1. The Art Unit of U.S. Patent application SN 09/092,297 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1644.
2. The amendment filed 11-30-99 has been entered into the record and has been fully considered. Claims 1-55 are pending. Claims 10-16, 25, 30, 33, 35, 38, 39 and 45-55 are under examination.
3. This application contains claims 1-9, 17-24, 26-29, 31, 32, 34, 36, 37 and 40-44 drawn to an invention nonelected without traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

**Rejections Maintained**

*Priority*

5. The priority date awarded claims 10-16, 25, 30, 33, 35, 38 and 39 is the filing date of the present application, 6/5/98 based on a lack of written description of full length sequences, for instance SEQ ID NO:5 and SEQ ID NO:17.

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Applicants have argued that support is provided for at least nucleotides 1-329 of the consensus sequence, and refers the examiner to SEQ ID NO:3 and Figure 2 of priority application SN 08/869,579.

These arguments have been fully considered but are not persuasive for the following reasons. A search of the parent application reveals that the consensus sequence in the parent is SEQ ID NO:3. Nucleotide sequence 819141 in the parent is SEQ ID NO:2. In comparison to instant SEQ ID NO:5, parent SEQ ID NO:3 possesses a nucleotide change at position 313 and parent SEQ ID NO:2 possesses two nucleotide changes at residues 12 and 247 (corresponding to nucleotides 78 and 313 of instant SEQ ID NO:5). Thus, the parent application fails to provide written description support for residues 66-329 of instant SEQ ID NO:5 as is instantly claimed by reference to sequence 819141. The priority date awarded instant claims is the instant filing date 6-5-97.

### **New Rejections Based on Amendment**

#### *Objections*

6. The amendment filed 11-30-99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: on page 55, in line 29, after "(SEQ ID NO:5)." the insertion of Sequence 819141 corresponds to nucleotide positions 66-329 of the consensus sequence.

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Applicant is required to cancel the new matter in the reply to this Office action.

A search of the parent application reveals that the consensus sequence in the parent is SEQ ID NO:3. Nucleotide sequence 819141 in the parent is SEQ ID NO:2. In comparison to instant SEQ ID NO:5, parent SEQ ID NO:3 possesses a nucleotide change at position 313 and parent SEQ ID NO:2 possesses two nucleotide changes at residues 12 and 247 (corresponding to nucleotides 78 and 313 of instant SEQ ID NO:5). Thus, the parent application fails to provide written description support for residues 66-329 of instant SEQ ID NO:5 as is instantly claimed by reference to sequence 819141. Thus, it is clear that sequence 819141 does not correspond to nucleotide positions 66-329 of the consensus sequence defined in the instant application as SEQ ID NO:5.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10-14, 33, 39 and 48-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 10-14, 33 and 48-55 are drawn to sequence 819141 which corresponds to nucleotide positions 66-329 of the consensus sequence, instant SEQ ID NO:5. A search of the

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parent application reveals that the consensus sequence in the parent is SEQ ID NO:3. Nucleotide sequence 819141 in the parent is SEQ ID NO:2. In comparison to instant SEQ ID NO:5, parent SEQ ID NO:3 possesses a nucleotide change at position 313 and parent SEQ ID NO:2 possesses two nucleotide changes at residues 12 and 247 (corresponding to nucleotides 78 and 313 of instant SEQ ID NO:5). Thus, the parent application fails to provide written description support for residues 66-329 of instant SEQ ID NO:5 as is instantly claimed by reference to sequence 819141.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 25 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the claim contradict. The preamble recites a polypeptide comprising at least one epitope (The skilled artisan recognizes an epitope as a region recognized by an antibody which is 6 amino acids, 18 nucleotides in length, as evidenced by Harlow & Lane, Antibodies, p. 76, lines 22-23.) and subsequently recites at least about 10 contiguous amino acids derived therefrom. Therefore the metes and bounds of the claim are indefinite to the skilled artisan. In addition, the method of claim 25 and the transfected cell of claim 30 appear to be incomplete since the host cells and transfected cells are not incubated under conditions sufficient to produce said polypeptide.

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***Claim Rejections - 35 USC § 102 or 103***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 10-14, 35 and 48-55 are rejected under 35 U.S.C. 102(b) as being anticipated by and also on sale and publicly used from Boehringer Mannheim Biochemical , 1991 catalog, page

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557. Claim 10 is drawn to test kits and polynucleotides comprising sequences that specifically bind to polynucleotides selected from the group consisting of SEQ ID NO:1, sequence 819141 and complements thereof. Boehringer teaches and sells random hexamer primers capable of detecting any polynucleotide sequence via binding thereto which is available in a container.

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14. Claims 10-16, 35, 38, 45, 46, and 48-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al, EST Database Accession No. AA195677 alignment, 19 May, 1997.

Claims 10-16, 25, 30, 35, 38 and 45-55 are drawn to polynucleotide sequences which bind to or encode contiguous amino acids of SEQ ID Nos:1-5, sequence 819141, and SEQ ID Nos:17-20. Hillier et al teach nucleotides which bind to or encode contiguous amino acids selected from the group consisting of SEQ ID Nos:1-5, sequence 819141, and SEQ ID NO:17-20, see alignment with SEQ ID NO:17, amino acids 102-117, backtranslation to nucleic acids 460-413. Thus, the reference teachings anticipate the claimed invention.

15. Claims 10-16, 35, 38, and 45-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al, EST database sequence accession AA456370, (see also IDS citation AI-1), June 6, 1997, aa14e02.r1 Soares NhHMPu S1 Homo sapiens cDNA clone 813242, 5' mRNA sequence. Claims 10-16, 25, 30, 35, 38 and 45-55 are drawn to polynucleotides which bind and encode contiguous amino acids, expression vectors and host cells containing such polynucleotides of SEQ ID NO's:1-5, 17-20 and sequence 819141. Hillier et al, disclose polynucleotides with 100%

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nucleic acid identity, to nucleotides encoding amino acids 36-117, from cDNA clones see attached alignment. Thus, the reference teachings anticipate the claimed invention.

16. Claims 10-16, 25, 30, 35, 38, and 45-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al, EST database sequence accession AA456370, (see also IDS citationAI-1), June 6, 1997, aa14e02.r1 Soares NhHMPu S1 Homo sapiens cDNA clone 813242, 5' mRNA sequence, or Hillier et al, EST Database Accession No. AA195677 alignment, 19 May, 1997 in view of Expression of Cloned Genes in E. coli, Sambrook et al, Cold Spring Harbor Laboratory , 1989. Claims 10-16, 25, 30, 35, 38 and 45-55 are drawn to polynucleotides which bind and encode contiguous amino acids, expression vectors and host cells containing such polynucleotides of SEQ ID NO's:1-5, 17-20 and sequence 819141. Hillier et al, disclose polynucleotides with 100% nucleic acid identity, to nucleotides encoding amino acids from cDNA clones, see attached alignments. However Hillier et al does not expressly teach a transfected host cell and a method of producing the polypeptide fragments using the host cell transfected with the polynucleotide fragments. Sambrook et al teach the expression of polypeptide fragments from cloned DNA sequences, using the DNA sequence, a vector and host cells transformed with the vector. Given the teachings of Sambrook et al it would have been *prima facie* obvious for one of skill in the art knowing the DNA sequence of Hillier and the techniques of Sambrook to insert the DNA sequence into an expression vector, transfect host cells and produce the polynucleotides and polypeptides as claimed. One of skill in the art would

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have been motivated to do so based on the ease and effectiveness taught by Sambrook et al for obtaining abundantly produced polypeptides for use in further analysis of the particular proteins properties and functional characteristics and would have expected success given the high skill in the art.

#### **Status of Claims**

17. No claims are allowed.

#### **Conclusion**

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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19. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.  
February 14, 2000

*Patricia A. Duffy*  
PATRICIA A. DUFFY  
PRIMARY EXAMINER